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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,043

06/27/2003

Darin G. Schaeffer

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INDIANAPOLIS OFFICE 27879
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INDIANAPOLIS, IN 46204-2033

EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

10/26/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/608,043

Applicant(s)

SCHAEFFER ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46-53 is/are allowed.
- 6) ☒ Claim(s) 29-32, 34-36, 38 and 41-45 is/are rejected.
- 7) ☒ Claim(s) 33, 37, 39 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 29, 46, and 49 are objected to because of an informality, which can be corrected as follows: In claim 29, in last two lines of the second paragraph; in claim 46, the last line of the second paragraph; and in claim 49, the last line of the claim; insert -- body-- after each occurrence of "sheath." Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 29-32, 34, 38, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (4,271,839). Fogarty et al. disclose:

Regarding claims 29 and 41, an introducer sheath including a radially expandable sheath body including a proximal portion and a distal portion and configured to have an axial opening folded portion (20b, fig. 7) and an insertion member (14 or 22b) for holding the folded distal portion of the sheath body in the non-expanded condition, where the sheath body is selectively movable between a non-expanded condition and an extended portion (20b, fig. 8), where the distal portion includes a folded portion when the sheath body is in the non-expanded condition and extended portion when the sheath body is in a radially expanded condition;

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Regarding claims 30, a handle (24/26);

Regarding claim 31, the insertion member (14) is a cannula having an inner lumen and a pusher member (22b);

Regarding claims 32 and 41, the handle (26) comprises a perimetrical opening;

Regarding claim 34, the sheath body comprises a low friction non-rigid material; and

Regarding claim 38, the handle (24) comprises ring member/handle (26) for engaging the sheath to the handle.

Note: The introductory statement of intended use ("for use in the percutaneous insertion of an article into a body opening") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Fogarty et al., which is capable of being used as claimed if one desires to do so.

4. Claims 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Heck (6,083,207). Regarding claim 41, Heck discloses a radially expandable sheath body (20) having an axial opening for passage of dilator (300) and a handle (18) engaged with the sheath body, the handle having an axial opening aligned with the sheath axial opening for passage of the dilator (300, see fig. 1), the handle further including a perimetrical opening (between two sections 114, 116) for removing the sheath body from the dilator. Heck further discloses:

Regarding claim 42, the handle (18) having a C-shape (fig. 4) and a circumferential opening (36, fig. 5); and

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Note: The introductory statement of intended use ("for use in the percutaneous insertion of an article into a body opening") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Heck, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heck (6,083,207) in view of Osborne (4,306,562). Heck discloses all the limitations of the claims, but Heck does not disclose the material of the sheath body as claimed. The material of the sheath as claimed is well known in the art for making introducer sheaths. For example, Osborne teaches a splittable introducer sheath made from flexible, low friction polytetrafluoroethylene (See claim 3 of the Osborne reference). Therefore, it would have been obvious to one having ordinary skill at the time the invention was made to make the sheath body, as disclosed by Heck, out of polytetrafluoroethylene. Such a material is biocompatible and flexible, and it would allow the sheath body to be easily inserted into a body lumen.

7. Claims 35-36 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. (4,271,839) in view of Osborne (4,306,562). Fogarty

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et al. disclose all the limitations of the claims, including a hemostatic valve (36); but do not disclose the material of the sheath body as claimed. The material of the sheath as claimed is well-known in the art for making an introducer sheath. For example, Osborne teaches an introducer sheath made from flexible, low friction polytetrafluoroethylene (See claim 3 of the Osborne reference). Therefore, it would have been obvious to one having ordinary skill at the time the invention was made to make the sheath body, as disclosed in Fogarty reference, out of polytetrafluoroethylene. Such a material is biocompatible and flexible, and it would allow the sheath body to be easily inserted into a body lumen.

Allowable Subject Matter

8. Claims 46-53 are allowed.
9. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses an introducer sheath system including, inter alia, a sheath body, an insertion cannula, and a dilator, where the sheath body include an axial opening, a non-expanded condition, and a radially-expanded condition; where the distal end of the sheath is foldable within an inner lumen of the cannula, and where the dilator has a tapered tip extending distal of the sheath body..

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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10. Claims 33, 37, 39, and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

11. Applicant's arguments filed on August 2, 2007 and regarding the rejection of claims based on the references of Fogarty et al. and Heck have been fully considered but they are not persuasive. That is, Fogarty et al. indeed discloses an introducer sheath usable in the percutaneous insertion of an article in a body opening. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. With respect to the Heck reference: Heck's device indeed is radially expandable, as claimed, from a non-expanded condition to an expanded condition. That is, the splitting of the sheath body produces protrusions that are movable in the radial direction with respect to the longitudinal axis of the sheath body. Applicant is reminded that the language itself of the claims must particularly point out and distinctly claim the subject matter which the Applicant regards as the invention, without limitations imported from the specification (e.g., the manner in which the sheath body radially expands). Limitations in the specification not included in the claim may not be relied upon to impart patentability to an otherwise unpatentable claim.

Applicant's arguments with respect to claim 45 have been considered but are moot in view of the new ground(s) of rejection.

The rejection of claims under 35 U.S.C.102 and based on the Aboul-Hosn reference is hereby withdrawn.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo
Primary Examiner

October 23, 2007